

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Application Number	09/171,909
Filing Date	May 9, 2001
First Named Inventor	Roy-Chowdhury
Art Unit	1644
Examiner Name	Ronald B. Schwadron
Attorney Docket Number	59046.000033

Sheet 1 of 7

U.S. PATENT DOCUMENTS

*Examiner Initials	Cite No.	DOCUMENT NUMBER Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
WJ	1.	US- 5,788,968	08-04-1998	Weiner	
	2.	US- 2003-0170258 A1	09-11-2003	Roy-Chowdhury, et al.	
	3.	US- 2004-0022768 A1	02-05-2004	Roy-Chowdhury, et al.	
	4.	US- 2004-0023909 A1	02-05-2004	Roy-Chowdhury, et al.	
		US-			
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FOREIGN PATENT DOCUMENTS

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		Country Code Number-Kind Code (if known)					YES	NO
M)	5.	WO	94/27622	12-08-1994	Beschoner		<input type="checkbox"/>	<input type="checkbox"/>
M)	6.	WO	98/37917	09-03-1998	Roy-Chowdhury, et al.		<input type="checkbox"/>	<input type="checkbox"/>
	7.	EP	0 914 163	05-12-1999	Roy-Chowdhury, et al.		<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>
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OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS

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			YES	NO
WBS	8.	Abandoned U.S. Appl. No. 08/808,629 filed February 28, 1997 (Roy-Chowdhury, et al.) (unpublished).	<input type="checkbox"/>	<input type="checkbox"/>
	9.	Go-pending U.S. Appl. No. 09/447,704 filed November 23, 1999 (Roy-Chowdhury, et al.) (unpublished).	<input type="checkbox"/>	<input type="checkbox"/>
	10.	Go-pending U.S. Appl. No. 09/356,294, filed July 16, 1999 (Roy-Chowdhury, et al.) (unpublished).	<input type="checkbox"/>	<input type="checkbox"/>
	11.	Go-pending U.S. Appl. No. 11/378,158, filed March 16, 2006 (unpublished).	<input type="checkbox"/>	<input type="checkbox"/>
WBI	12.	European Search Report dated June 29, 2001 for European Application No. EP 98912887.1, filed February 26, 1998.	<input type="checkbox"/>	<input type="checkbox"/>
PM	13.	European Search Report dated August 22, 2001 for European Application No. EP 00115423.6, filed February 26, 1998.	<input type="checkbox"/>	<input type="checkbox"/>
	14.	February 8, 2005 Translation of Substantive Examination Report (redacted) citing two (2) references for Israeli Patent Appl. No. 126,714.	<input type="checkbox"/>	<input type="checkbox"/>
	15.	International Search Report dated June 23, 1998 for International Application No. PCT/US98/03606, filed Feb. 26, 1998.	<input type="checkbox"/>	<input type="checkbox"/>
	16.	International Search Report dated September 15, 2004 for International Application No. PCT/US03/33178, filed October 17, 2003.	<input type="checkbox"/>	<input type="checkbox"/>
WBI	17.	Ali et al., "The use of DNA viruses as vectors for gene therapy," <u>Gene Therapy</u> , 1:367-384 (1994)	<input type="checkbox"/>	<input type="checkbox"/>
WBI	18.	Baggi, et al., "Oral Administration of an Immunodominant T-cell Epitope Downregulates Th1/Th2 Cytokines and Prevents Experimental Myasthenia Gravis", <u>The Journal of Clinical Investigation</u> , Vol. 104, No. 9, pg. 1287-1295, November 1999.	<input type="checkbox"/>	<input type="checkbox"/>

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			YES	NO
	19.	Benjamini, E. and Leskowitz, S. (Eds.), "Transplantation Immunology." Immunology: A Short Course, Ch. 19, 347-367 (Wiley-Liss, Inc. 2nd ed. 1991).	<input type="checkbox"/>	<input type="checkbox"/>
WZ	20.	Cantor, H.M. and Dumont, A.E., "Hepatic Suppression of Sensitization to Antigen Absorbed into the Portal System," <u>Nature</u> , 215:744-745 (1967)	<input type="checkbox"/>	<input type="checkbox"/>
ch	21.	Clare-Salzler et al., "Prevention of Diabetes in Nonobese Diabetic Mice by Dendritic Cell Transfer," <u>J. Clin. Invest.</u> , 90:741-748 (1992)	<input type="checkbox"/>	<input type="checkbox"/>
WZ	22.	Dai et al., "Cellular and humoral immune responses to adenoviral vectors containing factor IX gene: Tolerization of factor IX and vector antigens allows for long-term expression," <u>Proc. Natl. Acad. Sci. USA</u> , 92:1401-1405 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
WZ	23.	Engelhardt et al., "Ablation of E2A in recombinant adenoviruses improves transgene persistence and decreases inflammatory response in mouse liver," <u>Proc. Natl. Acad. Sci. USA</u> , 91:6196-6200 (1994)	<input type="checkbox"/>	<input type="checkbox"/>
WZ	24.	Eron et al., "Randomised trial of MNrgp120 HIV-1 vaccine in symptomless HIV-1 infection," <u>The Lancet</u> , 348:1547-1551 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
WZ	25.	Fang et al., "Gene Therapy for Hemophilia B: Host Immunosuppression Prolongs the Therapeutic Effect of Adenovirus-Mediated Factor IX Expression," <u>Human Gene Therapy</u> , 6:1039-1044 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
WZ	26.	Fauci, A., "Host factors and the pathogenesis of HIV-induced disease," <u>Nature</u> , 384:529-534 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
WZ	27.	Fukushima et al., "Effects of Cyclosporin A on the Induction of Oral Tolerance," <u>Oral Tolerance: Mechanisms and Applications: Annals of the New York Academy of Sciences</u> , 778:376-378 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
WZ	28.	Graham et al., <u>Methods in Molecular Biology</u> , 109-128 (The Human Press 1991)	<input type="checkbox"/>	<input type="checkbox"/>
WZ	29.	Guidotti et al., "High-Level Hepatitis B Virus Replication in Transgenic Mice," <u>J. Vir.</u> , 69(10):6158-6169 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
WZ	30.	Guzzetta et al., "Induction of Kidney Transplantation Tolerance Across Major Histocompatibility Complex Barriers by Bone Marrow Transplantation in Miniature Swine," <u>Transplantation</u> 51(4):862-866 (1991).	<input type="checkbox"/>	<input type="checkbox"/>

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			YES	NO
M	31.	Hancock et al., "Short Communication: Suppression of Insulinitis in Non-Obese Diabetic (NOD) Mice by Oral Insulin Administration Is Associated with Selective Expression of Interleukin-4 and -10, Transforming Growth Factor-beta, and Prostaglandin-E," Am. J. Path., 147(5):1193-1199 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
M	32.	Hirahara et al., "CD4+ T Cells Anergized by High Dose Feeding Establish Oral Tolerance to Antibody Responses when Transferred in SCID and Nude Mice," J. Immunol., 154:6238-6245 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
M	33.	Horwitz et al., "Synthesis and Assembly of Adenovirus 2: I. Polypeptide Synthesis, Assembly of Capsomeres, and Morphogenesis of the Virion," Virology, 39:682-694 (1969)	<input type="checkbox"/>	<input type="checkbox"/>
M	34.	Horwitz, M.S., "Adenoviridae and Their Replication," Virology, Ch. 60, 1679-1721 (Raven Press 2nd ed. 1990)	<input type="checkbox"/>	<input type="checkbox"/>
M	35.	Ilan et al., "Adoptive Transfer of Tolerance from Rats Centrally Tolerized to Adenoviral Antigens Allows Long-Term Adenovirus-Mediated Gene Therapy in Gunn Rats," Hepatology: AASLD Abstracts, 202A, 304 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
M	36.	Ilan et al., "Induction of Central Tolerance by Intrathymic Inoculation of Adenoviral Antigens into the Host Thymus Permits Long-term Gene Therapy in Gunn Rats," J. Clin. Invest., 98(11):2640-2647 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
M	37.	Ilan et al., "Transient Short Term FK-506 Treatment Permits Long Term Gene Expression Using Recombinant Adenoviruses Vectors," J. Hepatol.: Postgraduate Course and Abstracts of the 31st Annual Meeting of the European Association for the Study of the Liver, 23:73, WP3/019 (Supp. 1 1996)	<input type="checkbox"/>	<input type="checkbox"/>
M	38.	Jaffe et al., "Adenovirus-mediated in vivo gene transfer and expression in normal rat liver," Nature Genetics, 1:372-378 (1992)	<input type="checkbox"/>	<input type="checkbox"/>
M	39.	Kerr et al., "Apoptosis: A Basic Biological Phenomenon with Wide-Ranging Implications in Tissue Kinetics," Br. J. Cancer, 26:239-257 (1972)	<input type="checkbox"/>	<input type="checkbox"/>
M	40.	Kuby, J., "Cancer and the Immune System," Immunology, 573-596 (W.H. Freeman and Company 3rd ed. 1997)		
M	41.	Lederer, J. A. and A. K. Abbas, "Cytokines in Specific Immune Responses," Samter's Immunologic Diseases, Vol. I, Ch. 10, 129-141 (Little, Brown and Company 5th ed. 1995)		

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			YES	NO
my	42.	Maeda et al., "Conjugates of Anticancer Agents and Polymers: Advantages of Macromolecular Therapeutics in Vivo," <u>Bioconj. Chem.</u> , 3(5):351-362 (1992)	<input type="checkbox"/>	<input type="checkbox"/>
my	43.	Madsen et al., "Immunological Unresponsiveness Induced by Recipient Cells Transfected with Donor MHC genes," <u>Nature</u> , 332:161-164 (1988)	<input type="checkbox"/>	<input type="checkbox"/>
my	44.	Maizel et al., "The Polypeptides of Adenovirus: II. Soluble Proteins, Cores, Top Components and the Structure of the Virion," <u>Virology</u> , 36:126-136 (1968)	<input type="checkbox"/>	<input type="checkbox"/>
my	45.	Moller et al., "Cellular Mechanisms Underlying Differential Rejection of Sequential Heart and Lung Allografts in Rats," <u>Transplantation</u> , 55(3):650-655 (1993)	<input type="checkbox"/>	<input type="checkbox"/>
my	46.	Müller et al., "Relationship of antibodies against CD4 ⁺ T cells in HIV-infected patients to markers of activation and progression: autoantibodies are closely associated with CD4 cell depletion," <u>Immunology</u> , 79:248-254 (1993)	<input type="checkbox"/>	<input type="checkbox"/>
my	47.	Ninomiya, et al., "Intranasal Administration of a Synthetic Peptide Vaccine Encapsulated in Liposome together with an Anti-CD40 Antibody induces Protective Immunity against Influenza A Virus in Mice", <u>Vaccine</u> , Vol. 20, pg. 3123-3129, 2002.	<input type="checkbox"/>	<input type="checkbox"/>
my	48.	Pearson et al., "Induction of Transplantation Tolerance in Adults Using Donor Antigen and Anti-CD4 Monoclonal Antibody," <u>Transplantation</u> , 54(3):475-483 (1992)	<input type="checkbox"/>	<input type="checkbox"/>
my	49.	Peters et al., "Characterization and Tissue Specificity of a Monoclonal Antibody Against Human Uridine 5'-Diphosphate-Glucuronosyltransferase," <u>Gastroenterology</u> , 93:162-169 (1987)	<input type="checkbox"/>	<input type="checkbox"/>
my	50.	Prevec et al., "Use of Human Adenovirus-based Vectors for Antigen Expression in Animals," <u>J. Gen. Virol.</u> , 70:429-434 (1989)		
MI	51.	Rosengard et al., "Induction of Specific Tolerance to Class I-Disparate Renal Allografts in Miniature Swine with Cyclosporine," <u>Transplantation</u> , 54(3):490-497 (1992)		
my	52.	Roy-Chowdhury et al., "Bilirubin Mono- and Diglucuronide Formation by Human Liver <i>In Vitro</i> : Assay by High-Pressure Liquid Chromatography," <u>Hepatology</u> , 1(6):622-627 (1981)		
my	53.	Sachs et al., "Control of Programmed Cell Death in Normal and Leukemic Cells: New Implications for Therapy," <u>Blood</u> , 82(1):15-21 (1993)		

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			YES	NO
WJ	54.	Seglen, P. O., "Preparation of Isolated Rat Liver Cells," <u>Methods in Cell Biology</u> , Vol. 13, Ch. 4, 30-83 (1976)	<input type="checkbox"/>	<input type="checkbox"/>
WJ	55.	Sharabi et al., "Specific Tolerance Induction Across a Xenogeneic Barrier: Production of Mixed Rat/Mouse Lymphohematopoietic Chimeras Using a Nonlethal Preparative Regimen," <u>The Journal of Experimental Medicine</u> , 172:195-202 (1990)	<input type="checkbox"/>	<input type="checkbox"/>
WJ	56.	Smith et al., "New Approaches to Transplantation Tolerance," <u>Transplantation Proceedings</u> , 23(4):2157-2161 (1991)	<input type="checkbox"/>	<input type="checkbox"/>
WJ	57.	Sykes et al., "Bone Marrow Transplantation as a Means of Inducing Tolerance," <u>Seminars in Immunology</u> , 2:401-417 (1990)	<input type="checkbox"/>	<input type="checkbox"/>
WJ	58.	Takahashi et al., "Acute hepatitis in rats expressing human hepatitis B virus transgenes," <u>Proc. Nat. Acad. Sci. USA</u> , 92:1470-1474 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
WJ	59.	Takahashi et al., "Long Term Correction of Bilirubin-UDP-glucuronosyltransferase Deficiency in Gunn Rats by Administration of a Recombinant Adenovirus during the Neonatal Period," <u>J. Biol. Chem.</u> , 271(43):26536-26542 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
WJ	60.	Thomas et al., "Beneficial Effect of Cyclosporine in Posttransplantation Induction of Unresponsiveness of Renal Allografts in Rhesus Monkeys," <u>Transplantation Proceedings</u> , XX(1):134-136 (Suppl. 1 1988)	<input type="checkbox"/>	<input type="checkbox"/>
	61.	Thompson, C.B., "Apoptosis in the Pathogenesis and Treatment of Disease," <u>Science</u> , 267:1456-1462 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	62.	Towbin et al., "Electrophoretic transfer of proteins from polyacrylamide gels to nitrocellulose sheets: Procedure and some applications," <u>Proc. Natl. Acad. Sci. USA</u> , 76(9):4350-4354 (1979)	<input type="checkbox"/>	<input type="checkbox"/>
	63.	Trotman et al., "Azodipyrroles of Unconjugated and Conjugated Bilirubin Using Diazotized Ethyl Anthranilate in Dimethyl Sulfoxide," <u>Analytical Biochemistry</u> , 121:175-180 (1982)	<input type="checkbox"/>	<input type="checkbox"/>
	64.	Vandenbark et al., "Definition of Encephalitogenic and Immunodominant Epitopes of Guinea Pig Myelin Basic Protein (Gp-BP) in Lewis Rats Tolerized Neonatally with Gp-BP or Gp-BP Peptides," <u>J. Immunol.</u> , 153:852-861 (1994)	<input type="checkbox"/>	<input type="checkbox"/>
✓	65.	van der Lubben, Inez M. et al., "Chitosan and its Derivatives in Mucosal Drug and Vaccine Delivery," <u>European Journal of Pharmaceutical Sciences</u> , Vol. 14, pg. 201-207, 2001.	<input type="checkbox"/>	<input type="checkbox"/>

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WY	66.	Walter et al., "Successful expression of human factor IX following repeat administration of an adenoviral vector in mice," Proc. Natl. Acad. Sci. USA, 93:3056-3061 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	67.	Weiner, H.L. and Mayer, L.F. (Eds.), "Oral Tolerance: Mechanisms and Applications," Annals of the New York Academy of Sciences, Vol. 778 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	68.	Weiner, H.L., "Commentary: Oral tolerance," Proc. Natl. Acad. Sci. USA, 91:10762-10765 (1994)	<input type="checkbox"/>	<input type="checkbox"/>
	69.	Winkelstein, A., "Immunosuppressive Therapy," Basic and Clinical Immunology, Ch. 61, 766-779 (Appleton & Lange 7th ed. 1991)	<input type="checkbox"/>	<input type="checkbox"/>
	70.	Wyllie et al., "Cell Death: The Significance of Apoptosis," International Review of Cytology, 68:251-306 (1980)	<input type="checkbox"/>	<input type="checkbox"/>
	71.	Yang et al., "Inactivation of E2a in recombinant adenoviruses improves the prospect for gene therapy in cystic fibrosis," Nature Genetics, 7:362-369 (1994)	<input type="checkbox"/>	<input type="checkbox"/>
	72.	Yang et al., "Cellular and Humoral Immune Responses to Viral Antigens Create Barriers to Lung-Directed Gene Therapy with Recombinant Adenoviruses," J. Virol., 69(4):2004-2015 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	73.	Zarling et al., "HIV-infected humans, but not chimpanzees, have circulating cytotoxic T lymphocytes that lyse uninfected CD4 ⁺ Cells," J. Immunol., 144(8):2992-2998 (1990)	<input type="checkbox"/>	<input type="checkbox"/>
	74.	Zhao et al., "Skin graft tolerance across a discordant xenogeneic barrier," Nature Med., 2(11):1211-1216 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	75.	Ziegler, J.L. and Stites, D.P., "Hypothesis: AIDS is an Autoimmune Disease Directed at the Immune System and Triggered by a Lymphotropic Retrovirus," Clin. Immunol. Immunopathol., 41:305-313 (1986)	<input type="checkbox"/>	<input type="checkbox"/>

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